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MAY 25 2012

SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTED BY:

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CONTACT:

SUMMARY OF SAFETY A

Official Correspondent:
dr. Richard Albright
K-Laser USA
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Phone: 866-595-7749

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1185 W. Main Street,
Franklin, TN 37064
Phone: 866-595-7749
Fax: 615-261-3535
Email: ralbright@k-laserusa.com

1. DEVICE NAME (Trade/common, and classification):

Proprietary name: K-LASER
Common/usual name: K-Laser Cube 1, K-Laser Cube 2, K-Laser Cube 3, K-Laser Cube 4
Classification name: Infrared Lamp
Classification: Class II
Regulation Nos.: 21 CFR 890.5500
Product Codes: ILY

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2. PREDICATE DEVICES:

The device under submission is substantially equivalent to the predicate devices:

K091497 (K-1200);

K061656 (Laser-D68);

The device under submission is a family of laser emit a beam of coherent light in either continuous wave or pulse mode at the following wavelengths:

K-Laser Cube 1: 905nm; peak power: 10W;

K-Laser Cube 2: 800nm, 970nm; peak power: 15W;

K-Laser Cube 3: 800nm, 905nm, 970; peak power: 20W;

K-Laser Cube 4: 905nm; peak power: 10W.

3. PERFORMANCE STANDARDS:

The device conforms to the applicable requirements of 21 CFR section 1010 (Performance Standards for Electronic Products: General) and 21 CFR sections 1040.10 and 1040.11 (Performance Standards for Light-Emitting Products).

4. DESCRIPTION:

The devices under submission are a family of laser that emits a beam of coherent light in either continuous wave or pulse mode at the wavelengths previously described.

Each device is a table device, easy to transport, usable also without electrical net, thanks to a battery pack. It is composed of a touch screen for managing all the device functions, an emitter, an handpiece for the delivery of light, software and an on/off button to activate and deactivate the infrared emission.

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5. INTENDED USE/ INDICATIONS FOR USE:

Each device is indicated for emitting energy in the Infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.

6. SUBSTANTIAL EQUIVALENCE (SE) RATIONALE:

The devices under submission share the same intended use, similar design and functional features as the predicate devices without raising any issues of safety or effectiveness. Therefore, the devices under submission are substantially equivalent to the predicate devices K091497 (K-1200), K061656 (Laser-D68).

7. SAFETY AND EFFECTIVENESS:

There are no substantive differences between the product defined in this 510(k) submission and the predicate devices. They are similar to the technologies that are currently used in other similar medical devices. They were developed and documented under Eltech's mature Quality Managerment System, under The Quality System Regulation, 21 CFR Part 820, under design/change control, and verified/validated to applicable standards/guidance documents. Besides, Eltech's Quality Assurance System is certified by CERMET, notified body n. CE 0476, according to Annex II of 93/42 EEC Directive, transposed in Italy by Dlgs. n. 46 of 24 February 1997.

The devices are safe and effective when used as indicated in specific applications under a clinician's supervision/therapy program.

Date: 25th April 2012

Signature: _____

Francesco Zanata
Eltech s.r.l. President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Eltech S.R.L.
% K-Laser USA
Mr. Richard Albright
President
1185 West Main Street
Franklin, Tennessee 37064

MAY 25 2012

Re: K120604
Trade/Device Name: K-Laser
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: ILY
Dated: February 28, 2012
Received: February 28, 2012

Dear Mr. Albright:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

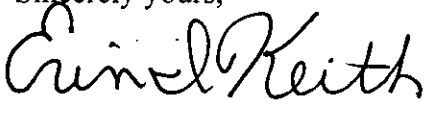
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120604

INDICATIONS FOR USE

Indications for Use:

K-laser Cube 1,2,3, and 4 device is indicated for emitting energy in the Infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.

Prescription Use ____X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120604